DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 28, 2014

Exatech®, Incorporated
Mr. Thomas McNamara
Regulatory Affairs Associate
2320 Northwest 66th Court
Gainesville, Florida 32653

Re: K141821
Trade/Device Name: Exactech® Alteon™ Neck Preserving Femoral Stems Sizes 6 and 7
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Regulatory Class: Class II
Product Code: LZO, LPH, KWY
Dated: July 30, 2014
Received: August 1, 2014

Dear Mr. McNamara:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K141821

Device Name: Exactech® Alteon™ Neck Preserving Femoral Stems Sizes 6 and 7

INDICATIONS FOR USE:

All Exactech Hip Systems are indicated for use in skeletally mature individuals undergoing primary surgery for hip replacement due to osteoarthritis, rheumatoid arthritis, osteonecrosis, post-traumatic degenerative problems of the hip, and for treatment of proximal femoral fractures where prosthetic replacement is determined by the surgeon as the preferred treatment. Components of Exactech Hip Systems are also potentially indicated for ankylosing spondylitis, congenital hip dysplasia, revision of failed previous reconstructions where sufficient bone stock is present, and to restore mobility resulting from previous fusion.

- Cemented femoral stems and cemented acetabular cups are intended for cemented fixation only.
- Press-fit femoral stems and acetabular cups are intended for press-fit fixation.
- Femoral heads and endoprostheses are intended for use in cemented and press-fit applications.

Prescription Use X **and/or** **Over-The-Counter Use** _____
(Part 21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

Please do not write below this line - use another page if needed.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Exactech® Alteon™ Neck Preserving Femoral Stems Sizes 6 and 7
Special 510(k) – 510(k) Summary

Sponsor: Exactech®, Inc
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Gainesville FL, 32653

Phone: (352) 377-1140
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FDA Establishment Number 1038671

Date: June 17, 2014

Contact Person: Thomas McNamara
Regulatory Affairs Associate
Telephone: (352) 377-1140
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Proprietary Name: Exactech® Alteon™ Neck Preserving Femoral Stems Sizes 6 and 7

Common Name: Femoral Hip Stem

Classification Name:

Prosthesis, Hip, Semi-Constrained, Metal/Ceramic/Polymer, Cemented Or Non-Porous, Uncemented (21 CFR Section 888.3353, Class II, Product Code LZO)

Prosthesis, Hip, Hemi-, Femoral, Metal/Polymer, Cemented Or Uncemented (21 CFR Section 888.3390, Class II, Product Code KWY)

Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Porous Uncemented (21 CFR 888.3358, Device Class: II, Product Code: LPH)

Legally Marketed Device to Which Substantial Equivalence Is Claimed:

Name	Manufacturer	510(k) Number
Exactech Novation LPI Prime Femoral Stem	Exactech, Inc	K121684

Indication for Use:

All Exactech Hip Systems are indicated for use in skeletally mature individuals undergoing primary surgery for hip replacement due to osteoarthritis, rheumatoid arthritis, osteonecrosis, post-traumatic degenerative problems of the hip, and for treatment of proximal femoral fractures where prosthetic replacement is determined by the surgeon as the preferred treatment. Components of Exactech Hip Systems are also potentially indicated for ankylosing spondylitis, congenital hip dysplasia, revision of failed previous reconstructions where sufficient bone stock is present, and to restore mobility resulting from previous fusion.

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Device Description
The Novation LPI Prime Femoral Stems are being re-branded as the Alteon Neck Preserving Femoral Stems.

The Alteon Neck Preserving Femoral Stems Sizes 6 and 7 are titanium press-fit prostheses featuring a 12/14 trunnion that is used on the femur side of a total or hemi hip arthroplasty. The proximal region of the stem is coated with titanium plasma sprayfor uncemented, biological fixation.

The proposed femoral stems are intended to mate with the following modular 12/14 femoral heads:

- Exactech Cobalt Chromium Alloy Femoral Heads (K041906)
- Exactech Ziramic Zirconia Femoral Heads (K050398, K060107)
- Exactech BIOLOX® forte Alumina Femoral Heads (K023964, K051682)
- Exactech *Biolox*Delta and *Delta*Option Femoral Heads and Adapters (K103012)
- AcuMatch L-series Unipolar endoprostheses (K010081)

The proposed Alteon Neck Preserving Femoral Stems Sizes 6 and 7are line extensions to the Novation LPI Prime Femoral Stems cleared in K121684. Both the predicate and proposed devices have the same intended use, general design features, and basic fundamental scientific technology. The proposed Alteon Neck Preserving Femoral Stems Sizes 6 and 7use the femoral neck geometry as the previously cleared Novation LPI Prime Femoral Stem Size 5.

Testing:
The following engineering analyses were conducted to demonstrate substantial equivalence of the proposed Alteon Neck Preserving Femoral Stems Sizes 6 and 7 to the predicate Novation LPI Prime Femoral Stem:

- Template Study
- Beam theory calculations to determine worst case configurations
- Finite Element Analysis

Substantial Equivalence Conclusion:
Results of engineering studies referenced in this 510(k) submission demonstrate the proposed Alteon Neck Preserving Femoral Stems Sizes 6 and 7 are substantially equivalent to cleared Novation LPI Prime Femoral Stem devices.